

Notice of Allowability	Application No.	Applicant(s)
	10/586,229	VOLLMERS ET AL.
	Examiner	Art Unit
	MARK HALVORSON	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Response filed 24 May 2011.
2. ☒ The allowed claim(s) is/are 1,2,5-10,13,14 and 58-63.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892)	5. <input type="checkbox"/> Notice of Informal Patent Application
2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____.
3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____	7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment
4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance
	9. <input type="checkbox"/> Other _____.
	/Misook Yu/ Supervisory Patent Examiner, Art Unit 1642

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jan Tittel on July 28, 2011.

The application has been amended as follows:

1. (Currently Amended) An isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof that specifically binds to a neoplastic cell or a cell of a pre-cancerous lesion, but does not specifically bind to a normal cell, wherein said isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof comprises a light chain variable region comprising a sequence shown in SEQ ID NO:29, and wherein said normal cell is not a cell of the glomerular, fascicular zone of the adrenal gland or an epithelial cell of the collection tubes of the kidney.

2. (Currently Amended) The isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof of claim 1, wherein said antibody or ~~functional~~ antigen-binding antibody fragment thereof further comprises a heavy chain variable region comprising amino acids 11-18, 36-43, and 82-104 of the sequence of SEQ ID NO:28.

3-4. (Cancelled)

5. (Currently Amended) The isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof of claim 1, wherein said antibody or ~~functional~~ antigen-binding antibody fragment thereof is capable of inducing apoptosis of said neoplastic cell or said cell of said pre-cancerous lesion, but does not induce apoptosis of said normal cell.

6. (Currently Amended) The isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof of claim 1, wherein said neoplastic cell is selected from the group consisting of Barrett's tumors and tumors of the esophagus, stomach, intestine, rectum, liver, gallbladder, pancreas, lungs, bronchi, breast, cervix, prostate, heart, ovary, and uterus.

7. (Currently Amended) The isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof of claim 1, wherein said pre-cancerous lesion is selected from the group consisting of dysplasia of the gastric mucosa, interstitial metaplasia of the stomach, inflammation of the gastric mucosa which is associated with the bacteria *Helicobacter pylori*, tubular and tubulovillous adenomas of the stomach, tubular adenoma of the colon, villous adenoma of the colon, dysplasia in ulcerative colitis, Barrett's dysplasia, Barrett's metaplasia of the esophagus, cervical intraepithelial neoplasia I, cervical intraepithelial neoplasia II, cervical intraepithelial neoplasia III, squamous epithelial metaplasia, squamous epithelial dysplasia of the bronchus, low grade and high grade prostate intraepithelial neoplasia (PIN), breast ductal carcinoma in situ (D-CIS), and breast lobular carcinoma in situ (L-CIS).

8. (Currently Amended) The isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof of claim 1, wherein said antibody or ~~functional~~ antigen-binding antibody fragment thereof is a ~~functional~~ antigen-binding antibody fragment of an antibody selected from the group consisting of V_L , V_H , F_V , F_C , Fab, Fab', and $F(ab')_2$.

9. (Currently Amended) The isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof of claim 1, wherein said antibody or ~~functional~~ antigen-binding antibody fragment thereof specifically binds to a polypeptide comprising the sequence of SEQ ID NO:6.

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10. (Currently Amended) An isolated nucleic acid molecule comprising nucleic acids 31-54, 106-129, and 244-312 of the sequence of SEQ ID NO:26, ~~and/or~~ and 82-96, 151-159, and ~~or~~ 268-300 of the sequence of SEQ ID NO:27.

11. (Cancelled)

12. (Cancelled)

13. (Currently Amended) A vector or a set of vectors comprising the nucleic acid sequence of SEQ ID NO:26; ~~or~~ and SEQ ID NO:27.

14. (Currently Amended) An isolated cell comprising the vector or the set of vectors of claim 13.

15-57. (Cancelled)

58. (Currently Amended) An isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof that specifically binds to a neoplastic cell or a cell of a pre-cancerous lesion, but does not specifically bind to a normal cell, wherein the antibody or ~~functional~~ antigen-binding antibody fragment comprises

a heavy chain comprising CDR1, CDR2, and CDR3 regions comprising amino acids 11-18, 36-43, and 82-104 of SEQ ID NO:28 respectively; and

a light chain comprising CDR1, CDR2, and CDR3 regions comprising amino acids 28-32, 51-53, and 90-100 of SEQ ID NO:29 respectively, and

wherein said normal cell is not a cell of the glomerular, fascicular zone of the adrenal gland or an epithelial cell of the collection tubes of the kidney.

59. (Currently Amended) The isolated antibody or ~~functional~~ antigen-binding antibody fragment of claim 58, wherein said antibody or ~~functional~~ antigen-binding antibody fragment is capable of inducing apoptosis of said neoplastic cell or said cell of said pre-cancerous lesion, but does not induce apoptosis of said normal cell.

60. (Currently Amended) The isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof of claim 1, wherein said antibody or ~~functional~~ antigen-binding antibody fragment thereof is an antibody.

61. (Currently Amended) The isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof of claim 1, wherein said antibody further comprises a heavy chain variable region comprising a sequence as shown in SEQ ID NO:28.

62. (Currently Amended) An isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof, wherein said isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof comprises a light chain variable region comprising the sequence of SEQ ID NO:29 and a heavy chain variable region comprising the sequence of SEQ ID NO:28, wherein said antibody or ~~functional~~ antigen-binding antibody fragment thereof is capable of inducing apoptosis of a neoplastic cell or a cell of a pre-cancerous lesion.

63. (Currently Amended) An isolated antibody or ~~functional~~ antigen-binding antibody fragment thereof, wherein the antibody or ~~functional~~ antigen-binding antibody fragment comprises

a heavy chain comprising CDR1, CDR2, and CDR3 regions comprising amino acids 11-18, 36-43, and 82-104 of SEQ ID NO:28 respectively; and

a light chain comprising CDR1, CDR2, and CDR3 regions comprising amino acids 28-32, 51-53, and 90-100 of SEQ ID NO:29 respectively, and

wherein said antibody or ~~functional~~ antigen-binding antibody fragment is capable of inducing apoptosis of a neoplastic cell or a cell of a pre-cancerous lesion.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached at (571) 272-0839. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson
Patent Examiner
571-272-6539

/Misook Yu/
Supervisory Patent Examiner, Art Unit 1642